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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, by ANDREW M. CUOMO, Attorney General of the State of New York, and THE CITY OF NEW YORK,	:	No. 07 Civ. 8434 (GBD)
Plaintiffs,	:	
- against -	:	
MERCK & CO., INC.,	:	
Defendant.	:	

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO REMAND FOR LACK OF FEDERAL SUBJECT MATTER JURISDICTION

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PRELIMINARY STATEMENT

Plaintiffs the State of New York and the City of New York hereby submit this Memorandum of Law in support of their motion to remand this action to the New York State Supreme Court, New York County, from which defendant Merck & Co., Inc. ("Merck") has improperly removed it.

Merck's removal of this action presents an easy case for remand because the Notice of Removal does not begin to satisfy the standards that Merck admits apply here. This action alleges violations solely of state and local law concerning Merck's campaign of misrepresentations, suppression and concealment about its pain medication Vioxx and causing false and fraudulent claims to be submitted to the New York State Medicaid program and the Elderly Pharmaceutical Insurance Coverage program. The sole ground for federal jurisdiction alleged by Merck in its Notice of Removal is that plaintiffs' claims fit into the narrow subcategory of state and local causes of action asserted that can be resolved *only* by deciding actually disputed and substantial issues of federal law that a federal court can entertain without disturbing the congressionally approved balance of responsibilities between federal and state courts. Merck did not demonstrate that this subcategory applies here for at least two reasons:

First, Merck failed to identify a single specific question of federal law that must be decided in order to determine Merck's liability. Without claiming such a question, Merck cannot satisfy its heavy burden of demonstrating federal subject matter jurisdiction. *See* Point I, *infra*.

Second, plaintiffs can establish Merck's liability on their state and local law claims without having to resolve any actually disputed and substantial questions of federal law that could appropriately be decided by a federal court. Plaintiffs' claims are about Merck's fraudulent conduct that was, for example, perpetrated through its army of highly scripted sales representatives, who sought to minimize physicians' concerns about the cardiovascular safety of

Vioxx to patients with established coronary artery disease. To establish liability under their causes of action, plaintiffs will show that Merck had knowledge of Vioxx's heightened risks to these patients, that Merck embarked on a campaign to minimize the significance of these risks and mislead doctors and consumers about these risks, and that doctors in New York wrote thousands of Vioxx prescriptions for these at-risk patients. Plaintiffs' causes of action thus involve garden variety state law, not federal law, and do not open the door to federal court. *See* Point II, *infra*.

BACKGROUND FACTS

A. The State and City's Complaint

Plaintiffs filed their complaint in the Supreme Court of the State of New York on September 17, 2007, seeking to recover from Merck the public and consumer funds spent on Vioxx for patients who had established coronary artery disease. Plaintiffs asserted six state and local statutory causes of action, claiming violations of the New York Social Services Law, the New York False Claims Act, the New York Executive Law, and the New York City False Claims Act. As is described more fully in the complaint, plaintiffs' claims are based upon Merck's fraudulent conduct.

Plaintiffs allege that as early as 1997, scientists within Merck expressed their concern about the negative cardiovascular impact of Vioxx, stating that "the possibility of increased CV [cardiovascular] events is of great concern." (Complaint ¶ 20). Merck's VIGOR study, completed in 2000, showed that, even though it excluded patients with a predisposition to developing serious cardiovascular problems, Vioxx patients were five times more likely to suffer heart attacks than patients on the pain medication naproxen. (*Id*. ¶¶ 26, 28).

In its communications to physicians and consumers, Merck sought to minimize the negative information about the cardiovascular effects of Vioxx. One method was to arm its sales representatives with "obstacle responses," which were scripts with which the representatives could overcome the "obstacle" to making sales posed by concerns about the risks of Vioxx. Using these obstacle responses, Merck misrepresented the negative findings about Vioxx and provided misleading information about the drug's cardiovascular safety. (*Id*. ¶¶ 34-53). Merck also sought to silence academic researchers who tried to convey the risks of Vioxx. With respect to at least one professor, Merck scientific personnel thought his presentations were "balanced," but a more senior manager threatened the professor's university with repercussions for "Merck-bashing." (*Id*. ¶¶ 59-64). Merck also engaged in a massive direct-to-consumer advertising campaign that failed to warn consumers about the cardiovascular risks of Vioxx. (*Id*. ¶ 70).

Not until September 2004 did Merck remove Vioxx from the market because of its excessive cardiovascular risk, including increased risk of heart attack and stroke. (*Id*. ¶ 5).

B. Merck's Notice of Removal

On September 28, 2007, Merck removed the case to this Court by filing its Notice of Removal (the "Notice"). In the Notice, Merck argued as its sole basis for federal subject matter jurisdiction that federal question jurisdiction exists under 28 U.S.C. §§ 1331 and 1441(b) pursuant to the Supreme Court's decision in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg*., 545 U.S. 308, 314-15 (2005).[1]

[1] Merck has moved to stay this action, and refused an offer to stipulate to stay only proceedings other than this remand motion. The stay motion is pending before this Court and, as plaintiffs describe more fully in their opposition to the stay motion, the remand motion should proceed so that the threshold question of this Court's jurisdiction can be resolved most efficiently and expeditiously.

ARGUMENT

This action rests on state and local law and does not give rise to federal subject matter jurisdiction. Federal courts have limited jurisdiction, and Merck, as the party asserting federal jurisdiction, has the burden of establishing a basis for it in its Notice of Removal. *In re Methyl Tertiary Butyl Ether Prods. Liability Litig.*, 488 F.3d 112, 124 (2d Cir. 2007) ("*In re MTBE*") ("In determining whether jurisdiction is proper, we look only to the jurisdictional facts alleged in the Notices of Removal."); *United Food & Commercial Workers Union, Local 919, AFL-CIO v. Centermark Prop. Meriden Square, Inc.*, 30 F.3d 298, 301 (2d Cir. 1994) ("defendant has the burden of establishing that removal is proper"). Remand is mandatory if Merck fails to sustain its burden. *In re Orthopedic "Bone Screw" Prods. Liability Litig.*, 132 F.3d 152, 155 (3d Cir. 1997). Merck, therefore, must overcome the presumption that this matter properly belongs in state court, and any questions concerning the existence of federal jurisdiction must be resolved in favor of state court jurisdiction. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) ("It is to be presumed that a cause lies outside [a federal court's] limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." (citations omitted)).

Federal courts are especially cautious in finding federal jurisdiction in a state law enforcement action brought in state court on behalf of the people. As the Supreme Court has stated, "considerations of comity make us reluctant to snatch cases which a State has brought from the courts of that State, unless some clear rule demands it." *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for So. Cal.*, 463 U.S. 1, 22 (1983).

Because Merck removed this case claiming subject matter jurisdiction based on the existence of a federal question, jurisdiction is determined by examining the allegations in plaintiffs' complaint. *See Rivet v. Regions Bank*, 522 U.S. 470, 475 (1998). "[T]he paramount

policies embodied in the well-pleaded complaint rule [are] that the plaintiff is the master of the complaint, that a federal question must appear on the face of the complaint, and that the plaintiff may, by eschewing claims based on federal law, choose to have the case heard in state court." *Caterpillar Inc. v. Williams*, 482 U.S. 386, 398-99 (1987). To have federal question jurisdiction where none appears from the face of the complaint, a "right or immunity created by the Constitution or laws of the United States must be an element, *and an essential one*, of the plaintiff's cause of action." *Franchise Tax Bd.*, 463 U.S. at 10-11 (*quoting Gully v. First Nat'l Bank*, 299 U.S. 109, 112 (1936)). That Merck might pursue federal defenses to plaintiffs' claims cannot serve as a basis for federal question jurisdiction. *Id*. at 7.

I. MERCK'S REMOVAL WAS WITHOUT BASIS BECAUSE MERCK FAILED TO IDENTIFY *ANY* SPECIFIC ISSUES OF FEDERAL LAW IN ITS NOTICE OF REMOVAL

Merck removed this case based on the argument that plaintiffs' claims arise under federal law pursuant to 28 U.S.C. §§ 1331 and 1441 as described in *Grable*. According to Merck, "As the Supreme Court explained in *Grable*, the test for whether a federal court should hear a case under this doctrine is not whether the federal statute provides a parallel private right of action, but whether the 'state-law claim necessarily raise[s] a stated federal issue actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.'" (Notice ¶ 10). Thus, to apply these standards, a court must examine the elements of the causes of action asserted in plaintiffs' complaint and determine whether liability can be established only if the Court first resolves issues of federal law that are actually disputed, substantial and appropriate to be heard in federal court.

Merck fails to satisfy these standards because it did not identify a single specific issue of federal law that must be decided for liability to be found here. Merck was required to set forth

the legal basis for removal in its Notice of Removal. *See In re MTBE*, 488 F.3d at 124 ("In determining whether jurisdiction is proper, we look only to the jurisdictional facts alleged in the Notices of Removal."). Because it failed to identify any specific issues of federal law, the Supreme Court's decision in *Grable* offers no ground for federal jurisdiction and this case must be returned to state court.

Rather than identify any specific issues of federal law, Merck, in its Notice of Removal, merely refers generally to two bodies of federal law -- the Food, Drug & Cosmetic Act ("FDCA") and federal Medicaid law (Notice ¶ 8). Referring to the mere existence of these laws and describing some of their provisions does not amount to setting out the detailed jurisdictional facts required by *Grable*. Merck argues that plaintiffs' claims "directly implicate" (Notice ¶ 8) and are "implicitly and explicitly premised" (Notice ¶ 11) on these federal bodies of law, but it failed to explain why liability under plaintiffs' causes of action can be found only if specific questions under these bodies of federal law are also determined. Arguing merely that claims "implicate" a federal law cannot amount to establishing that liability can be found only by resolving actually disputed, substantial questions of federal law. *See, e.g.*, *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804, 813 (1986) ("*Merrell Dow*") (describing the "long-settled understanding that the mere presence of a federal issue in a state cause of action does not automatically confer federal question jurisdiction").[2]

[2] Merck also claims that the "centrality of food and drug law to the allegations at issue in this matter are [*sic*] evidenced by Plaintiffs' own complaint, which repeatedly cites the FDA oversight of the highly regulated representations at issue in this case." (Notice ¶ 14). Merck cites to paragraphs 2 and 29-30 of the complaint, but any proper reading of those paragraphs demonstrates that Merck does not accurately describe them and they do not show plaintiffs' causes of action to require resolution of disputed, substantial federal issues.

II. MERCK CAN BE FOUND LIABLE UNDER PLAINTIFFS' CAUSES OF ACTION WITHOUT THE NEED TO DECIDE ACTUALLY DISPUTED, SUBSTANTIAL ISSUES OF FEDERAL LAW THAT CAN APPROPRIATELY BE HEARD BY A FEDERAL COURT

Even apart from Merck's failure to carry its burden in its Notice of Removal, remand to the state court is warranted because Merck can be found liable under plaintiffs' six state and local law causes of action on the basis of garden variety state law. The narrow ground for federal question jurisdiction described in *Grable* and many other cases is not applicable to such state and local claims, just as it has not been applicable in the overwhelming majority of other cases, including several cases in which Merck unsuccessfully advanced the same argument.

A. The Narrow Category of State-Law Cases Necessarily Requiring Resolution of Actually Disputed and Substantial Federal Questions

Grable belongs to a sizeable line of decisions where litigants have sought to invoke federal question jurisdiction by claiming a substantial federal ingredient so as to justify including a case within the federal courts' limited jurisdiction. The Supreme Court, however, has clearly recognized that the set of cases that can appropriately claim this basis of jurisdiction is a "special and small category." *Empire Healthchoice Assur., Inc. v. McVeigh*, 126 S. Ct. 2121, 2136 (2006).

In *Franchise Tax Bd.*, 463 U.S. at 1, the Supreme Court concluded that a state's action to recover state tax levies from a plan organized under federal ERISA law did not turn on a question of federal law. *Id*. at 28. To fit within federal question jurisdiction, the claim had to be one where "some substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims, or that the one or the other claim is 'really' one of federal law." *Id*. at 13.

In *Merrell Dow*, the Supreme Court further expounded on the availability of federal question jurisdiction over state law claims. There, a plaintiff argued it was entitled to a

rebuttable presumption of state law negligence because the defendant drug manufacturer had misbranded a pharmaceutical product in violation of the FDCA by failing to include on the label "adequate warning that it was potentially dangerous." 478 U.S. at 806. The Court granted the plaintiff's motion to remand because "the mere presence of a federal issue in a state cause of action does not automatically confer federal question jurisdiction." *Id*. at 813. The Court determined that Congress did not intend to provide access to federal courts where such questions under the FDCA were involved: "We simply conclude that the congressional determination that there should be no federal remedy for violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction." *Id*. at 814. In *Grable*, the Supreme Court further described the reasoning of *Merrell Dow*. In the context of the FDCA, it could hardly be assumed that Congress failed to provide such a right of action by oversight:

> *Merrell Dow* thought it improbable that the Congress, having made no provision for a federal cause of action, would have meant to welcome any state-law tort case implicating federal law "solely because the violation of the federal statute is said to [create] a rebuttable presumption [of negligence] . . . under state law." 478 U.S., at 811-812, 92 L. Ed. 2d 650, 106 S. Ct. 3229 (internal quotation marks omitted). In this situation no welcome mat meant keep out.

Grable, 545 U.S. at 319. Moreover, the *Grable* Court recognized that permitting federal jurisdiction over such garden variety state tort law claims that reference the FDCA would open the floodgates: "A general rule of exercising federal jurisdiction over state claims arising on federal mislabeling and other statutory violations would thus have heralded a potentially enormous shift of traditionally state cases into federal court." *Id*.

Grable was a very different case from *Merrell Dow*. There, the plaintiff was a delinquent taxpayer who brought suit in state court to quite title to land that the IRS had seized from it. Plaintiff argued that the IRS had failed to give proper notice of the seizure under a federal statute. To be successful on its complaint, plaintiff had to prove that a federal agency failed to give notice in the exact manner required under a federal statute. Federal question jurisdiction arose because the claim "depended on the interpretation of the notice statute in the federal tax law" and concerned the acts of a federal agency under that law. *Id*. In *Grable*, the absence of a federal private right of action was not dispositive because Congress would not have been expected to think that similar actions would "materially affect, or threaten to affect, the normal currents of litigation." *Id*. The Court recognized it would not be opening federal courts to a large number of new actions, because, unlike the situation with the FDCA, "it will be the rare state quiet title case that raises a contested matter of federal law, [and] federal jurisdiction to resolve disagreement over federal tax title provisions will portend only a microscopic effect on the federal-state division of labor." *Id*. at 315. Finally, while the Court eschewed a "single, precise, all-embracing test for jurisdiction over federal issues embedded in state-law claims," it stated that "the question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id*. at 314. As the Supreme Court later noted, the federal question at issue in *Grable* about the proper notice for seizures under federal law "was both dispositive of the case and would be controlling in numerous other cases." *Empire*, 126 S. Ct. at 2136 (citations and quotations omitted).[3]

[3] In *Empire* there was no federal question jurisdiction where, despite the federal involvement in creating an insurer's rights and obligations and despite that money recovered would be provided

Federal courts in New York have repeatedly applied this line of cases to reject efforts to expand federal jurisdiction over cases based on state law. In *In re MTBE,* the Second Circuit concluded that, despite presence of EPA regulations, the state law environmental injury claims did not give rise to federal question jurisdiction. Quoting *Gully*, 299 U.S. at 117, the Court stated "The most one can say is that a question of federal law is lurking in the background, just as farther in the background lurks a question of constitutional law, the question of state power in our federal form of government. A claim so far removed from plain necessity, is unavailing to extinguish the jurisdiction of the states." *See also Barbara v. New York Stock Exch., Inc.*, 99 F.3d 49, 54 (2d Cir. 1996) (no substantial federal question concerning the Exchange's enforcement of its internal rules even where a federal statute gave the Exchange the authority to regulate plaintiff's conduct, because the internal rules themselves were contractual and therefore interpreted solely under state law).

In *Caggiano v. Pfizer, Inc*., 384 F. Supp. 2d 689 (S.D.N.Y. 2005), the court granted a remand motion in a case similar to plaintiffs' case here. Plaintiffs there sued a drug manufacturer in state court under state law, claiming the manufacturer had caused a prescription drug to be used for unsafe purposes and had misled doctors and patients as to its safety and effectiveness. *Id*. at 690. Unlike the claims here, however, the complaint was "peppered with allegations that defendants violated various federal statutes and regulations." *Id*. at 690. The Court found no federal question jurisdiction:

> Here, the factual allegations set forth in the complaint state claims under New York law regardless of whether any federal law has been violated. Put another way, a jury could find defendants liable on each and every one of the eight claims without being required to determine whether any federal law had been violated. That facts

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to the United State Treasury, the contractual dispute arose only under state law and did not give rise to federal subject matter jurisdiction.

> alleged also may constitute violations of federal law (for which recovery is being sought in federal court) is neither here nor there.

Id. *See also New York v. Lutheran Ctr. for the Aging, Inc*., 957 F. Supp. 393, 400-401 (E.D.N.Y. 1997) (rejecting claim of federal question jurisdiction for recovery of Medicaid funds improperly expended in place of federal Medicare funds because, despite the presence of the federal Medicare program, the basis for liability turned on the interpretation of state law; the fact that the Medicaid funds "are generally derived from a federal program, or the result of a contract mandated by federal law will not alter this result").[4]

Other decisions involving state law claims about the marketing and sale of prescription drugs have overwhelmingly granted remand motions, and rejected arguments that state law claims gave rise to federal jurisdiction because of the FDCA and federal Medicaid laws. *See, e.g*., *Utah v. Eli Lilly & Co*., No. 2:07-CV-380 TS, 2007 U.S. Dist. LEXIS 65571 (D. Utah Sept. 4, 2007) (remanding action seeking to recover Medicaid funds from maker of prescription drug Zyprexa under state False Claims Act because no federal question was essential to resolution of the state law claims and congressional intent was that federal jurisdiction would not be proper);

[4] *See also New York v. Dell*, No. 1:07-CV-0572 (LEK/DRH), 2007 U.S. Dist. LEXIS 77152 (N.D.N.Y. Oct. 16, 2007) (rejecting federal question jurisdiction notwithstanding allegations of federal credit law violations because "Petitioner's right to relief does not necessarily depend upon federal law; Petitioner's claims are fully actionable under the state laws asserted"); *Barash v. Ford Motor Credit Corp*., No. 06-CV-6497 (JFB)(ARL), 2007 U.S. Dist. LEXIS 44641, at *14-15 (E.D.N.Y. June 20, 2007) (reference to federal law in section of complaint entitled "Applicable Precedents" did not convert state law claims into ones arising under federal law); *Elmira Teachers' Ass'n v. Elmira City School Dist*., No. 05-CV06513 CJS, 2006 U.S. Dist. LEXIS 3893, at *17-18 (W.D.N.Y. Jan. 27, 2006) (no federal jurisdiction over claims that school district negligently selected administrator of retirement plan created pursuant to federal tax laws); *Rubin v. Mastercard Int'l*, LLC, 342 F. Supp. 2d 217, 219-21 (S.D.N.Y. 2004) (no substantial federal question because state law claims alleging failure of credit card company to disclose credit card fees were actionable under state law irrespective of whether plaintiffs invoked federal Truth in Lending Act); *New York v. Justin*, 237 F. Supp. 2d 368, 374 (W.D.N.Y. 2002) (use of federal law as "guidepost" for state law claims did not give rise to federal question jurisdiction); *Eastern States Health & Welfare Fund v. Philip Morris, Inc*., 11 F. Supp. 2d 384, 395 (S.D.N.Y. 1998) (Sotomayor, J.) (New York law cause of action did not require reference to federal law to answer any of legal questions posited by removing defendants).

South Carolina v. Eli Lilly & Co., No. 7:07-18750HMH, 2007 U.S. Dist. LEXIS 56847 (D. S.C. Aug. 3, 2007) (remanding a Zyprexa case seeking recovery of Medicaid funds); *South Carolina v. Jannsen Pharmaceutica, Inc.*, No.6:07-1452-HMH, 2007 U.S. Dist. LEXIS 49904, at *5 (D.S.C. July 10, 2007) (remanding action seeking recovery of Medicaid funds concerning the prescription drug Risperdal); *Pennsylvania v. Eli Lilly & Co*., No. 07-1083, 2007 U.S. Dist. LEXIS 46946 (E.D. Pa. June 26, 2007) (remanding Zyprexa case seeking recovery of Medicaid funds); *Hawaii v. Abbott Labs, Inc*., 469 F. Supp. 2d 842 (D. Hawaii Oct. 27, 2006) (remanding False Claims Act case seeking recovery of Medicaid funds based on fraudulent setting of Average Wholesale Prices ("AWP") of prescription drugs); *Alaska v. Eli Lilly & Co*., No. 3:06-cv-88 TMB, 2006 U.S. Dist. LEXIS 52783 (D. Alaska July 28, 2006) (remanding Zyprexa case seeking recovery of Medicaid funds); *Missouri v. Mylan Labs, Inc*., No. 4:06CV603 HEA, 2006 U.S. Dist. LEXIS 32570 (E.D. Mo. May 23, 2006) (remanding action seeking recovery of state funds due to fraudulent setting of AWP); *Minnesota v. Pharmacia Corp*., No. 05-1395(PAM/JSM), 2005 U.S. Dist. LEXIS 27638 (D. Minn. Oct. 22, 2005) (remanding Medicaid Fraud Act case concerning setting of AWP); *Wisconsin v. Abbott Labs*, 390 F. Supp. 2d 815 (W.D. Wis. 2005) (remanding action seeking recovery of state funds due to fraudulent setting of AWP); *Pennsylvania v. TAP Pharmaceutical Prods., Inc*., 415 F. Supp. 2d 516 (E.D. Pa. 2005) (remanding AWP case).

Merck itself has in other cases sought to invoke federal question jurisdiction by arguing that state law claims required resolution of actually disputed and substantial issues of federal law. In those cases, however, Merck's arguments were unavailing and the courts remanded. Most significantly, a case brought by the State of Texas against Merck seeking to recover Medicaid funds spent on Vioxx has been remanded to state court twice. *Texas v. Merck & Co.*,

385 F. Supp. 2d 604 (2005); *Texas v. Merck & Co.*, No. A-06-CA-232-LY, slip op. at 3-4 (W.D. Tex. May 11, 2006) (Exhibit B to the accompanying Declaration of Randall M. Fox, dated October 26, 2007). Merck first removed the case shortly after receiving the complaint, and the court remanded because the state's causes of action did not depend upon actually disputed, substantial federal questions under the FDCA and federal Medicaid laws. 385 F. Supp. 2d at 604. Merck removed again when the state "conceded" in a discovery response that its Medicaid funding "is contingent upon the State's compliance with the federal laws, rules and regulations pertaining to Medicaid and is calculated according to federal law." Slip op. at 3-4. The court again rejected Merck's argument because "[t]he crux of Texas's action is what Merck said and did in order to convince Texas to add Vioxx to Texas's Medicaid Program," and, even with partial federal funding of the state's Medicaid program, the claims still did not require resolution of actually disputed, substantial federal questions. *Id*. at 6.[5]

B. Plaintiffs' Claims Are Based on State and Local Law and Do Not Require Resolution of Questions of Federal Law

The first step in any analysis under *Grable* and its line of cases is to examine the causes of action asserted, which, as noted in Point I, *supra*, is absent from Merck's Notice of Removal.

[5] *See also Fagin v. Gilmartin*, No. 03-2631 (SRC), 2007 U.S. Dist. LEXIS 7256 (D. N.J. Feb. 1, 2007) (remanding for lack of jurisdiction case alleging that Merck leadership engaged in mismanagement by failing to prevent inclusion of co-payment revenue in financials and maintain a system of internal controls to ensure compliance with federal securities laws: "That a court may be called upon to evaluate the offending conduct in light of what federal securities laws and regulations required does not federalize the claims for unjust enrichment, breach of fiduciary duty and contribution and indemnification. The claims pled require evaluation of the duties that are at their core defined by state law."); *Hawaii v. Abbott Labs.*, 469 F. Supp. 2d at 842 (remanding case after defendants, including Merck, had removed it because defendants failed to show interpretation of term "Average Wholesale Price" under federal law was actually disputed or substantial, rather case rested on tort claims under state tort law); *Shadie v. Aventis Pasteur, Inc.*, 254 F. Supp. 2d 509 (M.D. Pa. 2003) (remanding case asserting product liability, negligence and fraud against vaccine manufacturers, including Merck, because liability on state law claims did not necessarily require interpretation of or resort to National Vaccine Injury Compensation Act); *Haggerty v. Wyeth Ayerst Pharmaceuticals*, 79 F. Supp. 2d 182 (E.D.N.Y. 2000) (same).

Applying the case law described above, there is no basis for claiming federal question jurisdiction over plaintiffs' six state and local law causes of action. Instead, these claims will require the jury to assess Merck's statements about Vioxx through the lens of state and local statutory standards. These standards are not set by federal law, do not depend upon resolution of actually disputed or substantial issues of federal law, and, as described in the subsection C, *infra*, should be heard in state court as a matter of comity and federalism.

In their first cause of action, plaintiffs allege that Merck violated N.Y. Social Services Law § 145-b. "Social Services Law § 145-b (2) places personal liability on any individual who 'knowingly by means of a false statement or representation, or by deliberate concealment of any material fact' falsely obtains--or attempts to obtain--public funds, 'on behalf of himself or others.' Where public welfare benefits are obtained fraudulently by an entity . . . the individual supervising, overseeing, performing or conspiring to effectuate the fraudulent acts can be held personally responsible, and is liable for treble damages." *People v. Brooklyn Psychosocial Rehabilitation Inst.*, 185 A.D.2d 230, 234 (2d Dep't 1992). To succeed on this claim, plaintiffs will show that Merck knowingly conducted a campaign of misinformation and concealment about the risks of Vioxx to patients with existing coronary artery disease and that tens of millions of public and consumer dollars were spent on Vioxx for these patients.

In their second and third causes of action, plaintiffs allege that Merck violated the New York False Claims Act, N.Y. Finance Law § 187, *et seq*. Under Section 189(a) (the second cause of action), Merck would be liable for knowingly causing false and fraudulent Medicaid claims to be made for Vioxx prescriptions and refills for the at-risk population of persons with established coronary artery disease. Under Section 189(b) (the third cause of action), Merck could be liable for knowingly making and causing to be made false records and/or statements to

get false or fraudulent claims paid by plaintiffs. Plaintiffs will demonstrate that Merck has violated these provisions through, among other things, its communications with doctors and consumers that were false and misleading about the effect of Vioxx on at-risk patients. The sixth cause of action in the complaint similarly alleges violation of the City's False Claims Act, N.Y.C. Admin. Code §§ 7-801, *et seq*.

In their fourth and fifth causes of action, plaintiffs invoke the power of the Attorney General to remedy the repeated or persistent fraudulent acts of Merck, including the acts violating N.Y. Social Services Law § 145-b and the New York False Claims Act. Plaintiffs will, again, prove those fraudulent acts by showing that Merck undertook a campaign of misinformation. *See State v. Ford Motor Co*., 74 N.Y.2d 495, 502 (1989).

Liability under all of these causes of action depends upon matters commonly handled by state courts under state and local law. Such matters include Merck's level of knowledge and the misleading nature of its statements and omissions. The court's conclusion in *Caggiano* has equal force here: "[t]he duties alleged to have been breached here are not creatures of federal law." 384 F. Supp. 2d at 691. *See also Fin. and Trading, Ltd.. v. Rhodia S.A.*, No. 04 Civ. 6083, 2004 U.S. Dist. LEXIS 24148, at *21 (S.D.N.Y. Nov. 29, 2004) (no substantial federal question because "the right plaintiffs say they wish to vindicate is the right not to be lied to in a fashion that causes reliance and results in financial injury, not the narrower right not to be lied to in connection with a securities transaction regulated by federal law"). As was true in the case *South Carolina v. Jannsen*, 2007 U.S. Dist. LEXIS 49904, at *5, "liability will solely depend on [defendants'] respective breach of duties as defined and created by state law." *Id*. Accordingly, there are no issues of federal law that must be decided in this action, let alone actually disputed and substantial ones.

The court in *Pennsylvania v. Eli Lilly* aptly described the inapplicability of federal question jurisdiction to claims such as plaintiffs assert here:

> The Complaint in this case alleges a series of tortuous acts committed by the Defendants with the goal – and result – of increasing submissions of claims for non-medically accepted indications and non-medically necessary uses of each drug. The focus is on the Defendants' alleged "wide-spread fraudulent statements and conduct, and pervasive false and misleading marketing, advertising and promotion of their antipsychotic drugs," as well as the Defendants' alleged failures to warn and affirmative misrepresentations with respect to known dangerous side effects. (Compl. ¶ 62.) To prevail, the Commonwealth must prove that the Defendants' fraudulent promotion of their respective drugs caused false of fraudulent claims to be submitted to Medicaid and PACE for reimbursement, and that the Defendants' failure to provide adequate warnings of known risks caused Commonwealth Medicaid and PACE participants to sustain injuries for which Medicaid and PACE provide treatment. Looked at analytically and closely, no violation of federal law is asserted in the Complaint as a basis for liability.

2007 U.S. Dist. LEXIS 46946, at *10-11. The same reasoning applies to the New York state and local causes of action asserted here.

In its Notice of Removal, Merck points to two cases in support of its claim of federal question jurisdiction, but they are unavailing. *In re Zyprexa Prods. Liab. Litig*., 375 F. Supp. 2d 170, 172 (E.D.N.Y. 2005), involved a state's claims that a drug manufacturer marketed a prescription drug specifically in violation of federal law. That court denied the remand motion based on the claims asserted. In the present action, plaintiffs do not claim that Merck violated federal law, and the *Zyprexa* case is inapplicable. Notable, too, is that this *Zyprexa* decision runs counter to the long list of cases described above, many of which concluded, consistent with *Franchise Tax*, *Merrell Dow*, *Grable* and *Empire*, that more than just references to violations of federal law are required for federal question jurisdiction.

Merck also cites to *County of Santa Clara v. Astra USA, Inc*., 401 F. Supp. 2d 1022 (N.D. Cal. 2005). In that case, a county in California claimed that the manufacturers of over-the-counter medications charged prices that exceeded maximum prices allowed by a federal statute and a contract between the federal government and the manufacturers that was explicitly governed by federal common law. The court examined each claim asserted by the county and found that, under each one, liability required a determination of a specific question of federal law: "For this case to be resolved on its merits, at least one of the federal issues embedded in the complaint must be addressed. There is simply no other way." *Id*. at 1025. The claims of plaintiffs in the present action are dissimilar. Plaintiffs do not claim violations of any federal law and are not contractually bound to apply federal common law, rather they base their claims on Merck's misconduct in misleading doctors and consumers about the safety of Vioxx for at-risk patients and they claim violations of state and local law standards.

C. Remand Should Be Granted in the Interests of Comity and Federalism

The Supreme Court in *Grable* instructed that the question of whether federal question jurisdiction exists over purely state law claims must, as a matter of comity and federalism, take into account whether "a federal forum may entertain [the case] without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314. A court's finding that Congress did not intend federal jurisdiction to extend to a type of case is a "veto" of such jurisdiction even when an actually disputed, substantial federal question exists. *Id.* at 313. "This principle is even more relevant when, as here, the case was brought by the State itself." *New York v. Dell*, 2007 U.S. Dist. LEXIS 77152, at *9.

Under *Grable*, a court must look at the contextual clues that reveal whether Congress intended the federal courts to hear the type of state law claim in which a disputed and substantial federal question is embedded. *Id*. at 318-19. *Grable* cited such contextual clues as whether

Congress provided a federal private cause of action to vindicate the federal right or interest and whether the state remedies for violation of the federally created interest are preempted. *Id*. As part of this analysis, a court must also evaluate how extending federal jurisdiction to the type of action at issue would affect the volume of cases filed originally or removed to federal court. *Id*.

In the present action, all of the contextual clues signal the absence of any congressional intent to have cases such as plaintiffs' heard in a federal court. *First,* Congress clearly demonstrated its intent by failing to include a private right of action in the FDCA. The *Grable* Court recognized that, where federal questions are claimed to arise under the FDCA, as in *Merrell Dow*, the absence of a private right of action conclusively demonstrates the congressional intent that claims would be heard by a state court. *Id*. at 319. To rule otherwise would herald "a potentially enormous shift of traditionally state cases into federal court." *Id*. The influx of state law cases into federal court would be enormous, as is evidenced by the 19,100 Vioxx cases against Merck that were pending in state courts as of the end of 2006. *See* Merck 2006 Form 10-k, at 22, http://www.merck/finance/proxy/2006_form_10-k.pdf.[6] The numerous cases cited above that involve claims about other prescription drugs further illustrates that the concern about opening the federal court doors to a huge influx of state law personal injury, fraud and Medicaid cases is real and substantial.

Like the FDCA, the federal Medicaid laws do not provide for a private right of action or a federal ground for liability, thus indicating a congressional intent that jurisdiction remain with state courts. *See Lutheran Center for the Aging*, 957 F. Supp. at 400 ("However, neither the [federal Medicaid] statute nor the regulations provide the grounds for liability. Any basis for liability turns on an interpretation of state law." (internal citations omitted)). Providing federal

[6] An additional 8,300 cases were pending in federal court, mostly under diversity jurisdiction. *Id*.

jurisdiction over Medicaid cases would also risk a large influx of state law cases into federal courts. If, as Merck asserts in the Notice of Removal (at ¶ 15), the fact that the federal government provides some funding of state Medicaid programs were sufficient to permit federal jurisdiction over claims seeking to recover Medicaid funds dissipated through fraud, then tens of thousands of previously state cases around the country could be filed in or removed to federal court, even where the allocation of recovered proceeds is not an issue for liability.[7]

Second, Congress expressed its intent that suits, such as plaintiffs', to recover Medicaid funds would be handled under state law and in state courts by expressly delegating to the states the administration and operation of Medicaid programs. Most importantly, it delegated to the states the functions plaintiffs are seeking to carry out in this case: recovery of ill-gotten Medicaid funds. *See* 42 U.S.C. § 1396a(a) (a state Medicaid plan must provide that the state take reasonable measures to ascertain the legal liability of third parties and seek recovery from them). "Where a federal statute such as Medicaid requires a state to enforce liability against a third party but does not provide the ground for liability, nor require establishment of a ground for liability, federal jurisdiction will not lie." *Lutheran Center for the Aging*, 957 F. Supp. at 403.

Third, Congress expressed its intent by providing strong encouragement for states to establish Medicaid Fraud Control Units so that the states themselves could pursue the recovery

[7] In any event, the mere fact of federal funding does not provide a basis for federal jurisdiction. *See Jobs, Training & Servs. v. East Tex. Council of Gov'ts*, 50 F.3d 1318, 1326-27 (5th Cir. 1995) (court lacked federal question jurisdiction over state law claims involving contract using federal grant money where Congress delegated responsibility to ensure financial responsibility and compliance with federal mandates to state); *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, No. 01-12257-PBS, 2007 U.S. Dist. LEXIS 68193, at *19 (D. Mass. Sept. 17, 2007) (federal government's entitlement to 50% of recovery of Medicaid funds did not "federalize" state law claims); *Eastern States Health & Welfare Fund*, 11 F. Supp. 2d at 391 (federal question of whether plaintiff benefit plans could prove under federal law obligation to pay recovered funds to subrogated plan participants insubstantial in case seeking to impose liability on tobacco companies for medical expenses of plan members).

of Medicaid funds obtained by fraud. *See* Pub. L. 95-142, § 17 (authorizing funding to, as the Senate Finance Committee noted, "help establish Medicaid Fraud Control Units patterned after the successful unit in New York").

Fourth, Congress expressed its intent by providing specific incentives for states to enact their own False Claims Acts which provide an additional tool for states to recover improperly obtained Medicaid funds. *See* Deficit Reduction Act of 2005, Pub. L. 109-171, § 6023 (entitled "Encouraging the Enactment of State False Claims Acts" and permitting states with such laws to retain a larger percentage of Medicaid recoveries). New York enacted its False Claims Act in April 2007 and plaintiffs have asserted claims under that state law here. *See* Complaint ¶¶ 82-93, N.Y. Finance Law §187, *et seq*.

New York State, in fact, has an enormous interest in pursuing the recovery of Medicaid funds dissipated by fraud. Medicaid is the single largest budget item for the State of New York. *See* 2007-2008 New York State Executive Budget Briefing Book, Program Overview ("If no action is taken to curb costs, total Medicaid spending in New York will reach $48.7 billion in 2007-08, or nearly 35 percent of the proposed State Budget."), http://publications.budget.state.ny.us/fy0708littlebook/HealthCare.html.

CONCLUSION

For all the foregoing reasons, the State and City respectfully request that this Court remand this case to the New York State Supreme Court for the County of New York.

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